

V980/BET1000 Behind Ear Gentle Touch Thermometer

K103839/54

JUN - 6 2011

510(k) Summary

1.0 Preparation Date:

December 15, 2010 (Revised on May 25, 2011)

2.0 Submitted By:

KAZ USA, Inc.
250 Turnpike Rd
Southborough, MA 01772

FDA CDRH DMC

Primary Contact Person/Prepared by:

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Kaz, USA, Inc
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MAY 27 2011

Received

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3.0 Device Identification:

3.1 **Trade Name**

Behind Ear Gentle Touch Thermometer-
Models V980(US, EU and Canada)/ BET 1000 (International)

3.2 **Common Name**

Contact Skin Surface Thermometer

3.3 **Classification Name**

Thermometer, Clinical, Electronic
(21CFR 880.2910: Product code - FLL)

4.0 **Predicate Device:**

Predicate	Manufacturer	Docket Number
Up-Grade Forehead Thermometer	Medisim Ltd.	K032362

5.0 **Device Description:**

The over-the-counter Behind Ear Gentle Touch Thermometer – Models V980/ BET 1000 is a hand-held, battery powered device designed to measure human body temperature by detecting heat flow on the skin directly behind the ear lobe as a measurement site, by using the heat conduction principal and prediction. The skin area over the posterior auricular artery passing behind the earlobe is the measurement site, which is very close to the cantharid artery. These arteries carry blood to the brain and therefore the site is the best external place to measure temperature.

The Behind Ear Gentle Touch Thermometer is designed to calculate the maximum temperature of a probe in contact with the body site by heat transfer data and mathematical algorithm. The temperature reading range is from 95.0° F to 107.6° F (35°C to 42 °C) and the time of measurement is about 1 second.

6.0 **Intended Use:**

A non-sterile, reusable clinical thermometer intended for the intermittent determination of the human's body temperature using behind the patient's earlobe as the measurement site on people of all ages.

7.0 **Statement to Conform to the Consensus Standards (Verification)**

The Behind Ear Gentle Touch Thermometer conforms to the following FDA recognized consensus standards and other standards that include:

- 1) ASTM E1112-00 (Reapproved 2006)- Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature and;
- 2) Clinical accuracy test requirements established in the standard of ASTM E1965-03 (Clinical part only)- Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature;
- 3) IEC 60601-1: Medical Electrical Equipment: General requirements for Safety, Requirements and Tests.
- 4) IEC 60601-1-2: Medical Electrical Equipment- Part 1: General Requirements for Safety, Electromagnetic Compatibility, Requirements and Tests.
- 5) AAMI / ANSI / ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing- and appropriate parts.

- 6) ISO 10993-5: Biological Evaluation of Medical Devices: Part 5: Tests for In-vitro cytotoxicity.
- 7) ISO 10993-10: Biological Evaluation of Medical Devices: Part 10: Tests for Irritation and Sensitization.
- 8) ISO 14971:2007 2nd edition: Application of Risk Management to Medical Devices

Data supporting conformance with these standards is available from KAZ Inc and is attached as part of this submission.

8.0 **Validation Results:**

1. Clinical Study to show substantial equivalence:

A comparison study and clinical repeatability testing was performed on the following four age groups: 0-24 months, 24 months- <5 years, 5 years- <18 years, and 18 years and older in accordance with ASTM E1965-03 to compare the Behind Ear Gentle Touch Thermometer with the predicate Up-Grade Forehead Thermometer (K032362). The reference or the gold standard used was the Braun Infra Red Ear 4000 Series Thermometer (K031968/K101747). This clinical comparison study demonstrated that the Behind Ear Gentle Touch Thermometer is as good as (non-inferior or substantially equivalent to) the previously approved Up-Grade Forehead Thermometer (K032362) in all age groups with respect to the bias and standard deviation in comparison to the Braun Infra Red Ear 4000 Series Thermometer (K031968/K101747). The skin temperatures obtained with the Behind Ear Gentle Touch Thermometer were highly related when compared to the predicate device, where temperatures were measured at forehead sites. The clinical bias with stated uncertainty and clinical repeatability as defined in the ASTM E1965-03 standard were within clinical acceptability (bias less than 0.2 deg C or 0.4 deg F). The clinical repeatability of the Behind Ear Gentle Touch Thermometer was statistically and clinically acceptable (less than 0.3 deg C or 0.58 deg F as required per EN 12470).

9.0 **Conclusion:**

Based on the safety and performance testing and the compliance with the acceptable voluntary consensus standards, we conclude that the Behind Ear Gentle Touch Thermometer is substantially equivalent to its predicate device cited above and does not raise any new questions of safety and/or effectiveness.

10.0 **Similarities/Differences of the proposed candidate device when compared to the predicate:**

10.1 Intended Use

The predicate device, the Up-Grade Forehead Thermometer is intended for the intermittent determination of the human's body temperature for people of all ages. The intended use and indications for use of the predicate and the KAZ Behind Ear Gentle Thermometer are similar. However, the only difference is measurement location or site. The predicate device uses the temporal artery area of the forehead, while the KAZ Behind Ear Gentle Thermometer uses the posterior auricular artery behind the ear lobe as the measurement site.

10.2 Materials

Materials used in the manufacture of the KAZ Thermometer are similar to the predicate device. All skin contacting materials used in the new thermometer have been tested in accordance with ISO 10993-1 and FDA Blue book memo G 95-1 for both Thermometers and the corresponding test reports are included in this submission.

10.3 Design

The design of the KAZ Thermometer is similar to the predicate device and is typical for a surface, thermistor sensor thermometer.

10.4 Operational Principles

The KAZ Thermometer is a handheld device, containing an On/Off switch, probe, microcontroller and LCD screen to control the device and take measurements. The operating principles based on heat transfer to the skin and predictive algorithms are similar to the predicate device.

10.5 Technology

A technology similar to that of the predicate was used in the design of the Behind Ear Gentle Touch Thermometer as is employed in the design of the predicate device. The only difference is the firmware and microcontroller.

10.6 Safety and Performance

KAZ has provided statements that its Behind Ear Gentle Touch Thermometer conforms to the following FDA recognized consensus standards and other standards that include:

- 1) ASTM E1112-00 (Reapproved 2006)- Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature and;
- 2) Clinical accuracy test requirements established in the standard of ASTM E1965-03 (Clinical part only) - Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature;
- 3) IEC 60601-1:1995: Medical Electrical Equipment: General requirements for Safety, Requirements and Tests.
- 4) IEC 60601-1-2: Medical Electrical Equipment- Part 1: General Requirements for Safety, Electromagnetic Compatibility- Requirements and Tests.
- 5) AAMI / ANSI / ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing- and appropriate
- 6) ISO 10993-5: Biological Evaluation of Medical Devices: Part 5: Tests for In-vitro cytotoxicity.
- 7) ISO 10993-10: Biological Evaluation of Medical Devices: Part 10: Tests for Irritation and Sensitization.
- 8) ISO 14971:2007 2nd edition: Application of Risk Management to Medical Devices

11.0 **Similarities/Differences of the proposed candidate device when compared to the predicate:**

Aspects	Predicate	Candidate
Classification	21CFR 880.2910	Same
Product Code	FLL	Same
FDA Class	II	Same
Intended Use	A non-sterile, reuseable clinical thermometer intended for the determination of the human's body temperature.	A non-sterile, reuseable clinical thermometer intended for the intermittent determination of the human's body temperature for people of all ages.
Operation	Hand held-Manually operated	Same
Sensor	Thermistor	Same
Materials	Common Materials- including an impact resistant casing and water resistant sealed sensor. Biocompatible metals and resins.	Same
Standards Met for Bench and Clinical Performance	<ol style="list-style-type: none"> 1) ASTM E1112-Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature 2) The clinical accuracy test section of ASTM E1965-03- Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature 	Same
Standards met for Safety	<ol style="list-style-type: none"> 1.) IEC/EN 60601-1: Medical Electrical Equipment: General requirements for Safety, Requirements and Tests. 2. AAMI / ANSI / ISO 10993-1:2003(E), Biological evaluation of medical devices, Part 1 and G95-1: Evaluation and testing 	Same

12. Conclusion:

Based on the safety and performance testing and compliance with acceptable voluntary standards, the Behind Ear Gentle Touch Thermometer is substantially equivalent to its predicate device cited above and does not raise any new safety and/or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Raj S. Kasbekar
Vice President Regulatory Affairs
KAZ, Incorporated
250 Turnpike Road
Southborough, Massachusetts 01772

JUN - 6 2011

Re: K103839
Trade/Device Name: Behind Ear Gentle Touch Thermometer-Model V980
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 25, 2011
Received: May 27, 2011

Dear Mr. Kasbekar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

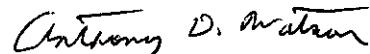
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statements

Indications for Use

510(k) Number (if known):

Device Name: **Behind Ear Gentle Touch Thermometer**

Indications for Use:

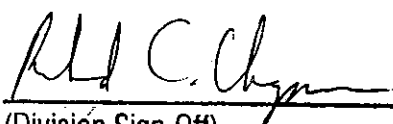
The Behind Ear Gentle Touch Thermometer (Models V980/BET 1000) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature using behind the earlobe as the measurement site on people of all ages.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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